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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,327	05/30/2000	Michael T. Taylor	22660-0027US	1734

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EXAMINER

REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

4248

Office Action Summary	Applicant No.	Applicant(s)	
	09/584,327	TAYLOR ET AL.	
	Examiner	Art Unit	
	David A Redding	1744	

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 May 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6, 7 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: group I, claims 82-85; group II, claims 1-19,30-39; group III, claims 20-29; group IV, claims 41-54,68-81; group V, claims 55-67 .

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

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In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Schmonsees on 7/17/02 a provisional election was made without traverse to prosecute the invention of group I, claims 83-85. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-82 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

2. The amendment filed 8/13/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claims 83 and 84, the claims define a "micro-sonicator" and "micro-fluidic system". The examiner has reviewed the specification and there is no support in the specification for such embodiments. Claims 83-85 specify "ultrasonic transmission media". The examiner has reviewed the specification and the only reference is to a lysing reagent.

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It is the examiners opinion that the term "ultrasonic transmission media" would include materials other than lysing agents and therefore constitutes subject matter which was not originally disclosed. Further, the claims specify "ultrasonic excitation of the transmission media". A review of the specification reveals that there is no support in the specification for such an embodiment.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 83-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 83 and 84, the claims define a "micro-sonicator" and "micro-fluidic system". The examiner has reviewed the specification and there is no support in the specification for such embodiments. Claims 83-85 specify "ultrasonic transmission media". The examiner has reviewed the specification and the only reference is to a lysing reagent. It is the examiners opinion that the term "ultrasonic transmission media" would include materials other than lysing agents and therefore constitutes subject matter which was not originally disclosed. Further, the claims specify "ultrasonic excitation of the transmission media".

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A review of the specification reveals that there is no support in the specification for such an embodiment.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 83-85 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,100,084 (Miles et al.).

Claims 83-85 have priority only to the filing date (5/30/2000) of the instant application. Applicant asserts priority to provisional application 60/136,703, filing date 5/28/1999. However, a review of the specification of the provisional document reveals that claims 83-85 are not supported by the disclosure within the provisional document. Actually, the provisional document is directed away from a “micro-sonicator” and designed to handle larger sample sizes (col.2, lines 21-col.3, line 26).

Also there is no disclosure within the provisional document of “ultrasonic excitation”; “ultrasonic transmission media”; or “ultrasonic waves”. Further, the provisional document does not disclose a membrane, rather specifies a gasket.

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Accordingly, the priority of claims 83-85 is the filing date of the instant application, which qualifies U.S. Patent 6,100,084 as prior art. As stated in applicants response filed 7/13/01, claims 1-14, 17, and 18 correspond to claims 83-85, thus anticipating claims 83-85.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 84 and 85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/006,848 in view of USP 5,856,174. Claim 1 in the '848 application defines a device for lysing comprising, in part, a lysing chamber and an ultrasonic transducer which is coupled to the wall of the lysing chamber. The claim does not specify a transmission media. The '174 patent discloses a similar lysing chamber in which is added deionized water as a transmission media (example #1).

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Accordingly, it would be obvious to one skilled in the art to include the transmission media disclosed in the US patent into the device claimed in the '848 application, especially in view of the fact that both devices are used for lysing.

This is a provisional obviousness-type double patenting rejection.

9. Claims 84 and 85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 of copending Application No. 10/006,850 in view of USP 5,856,174 ('174). Claim 3 in the '850 application defines a device for lysing comprising, in part, a lysing chamber and an ultrasonic transducer which is coupled to the wall of the lysing chamber. The claim does not specify a transmission media. The '174 patent discloses a similar lysing chamber in which is added deionized water as a transmission media (example #1). Accordingly, it would be obvious to one skilled in the art to include the transmission media disclosed in the US patent into the device claimed in the '850 application, especially in view of the fact that both devices are used for lysing.

This is a provisional obviousness-type double patenting rejection.

10. Claims 84,85, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13,14,19 of U.S. Patent No. 6,391,541 B1 (Petersen et al.) in view of USP 5,856,174 ('174). Claims 13,14,19 in the Petersen et al. patent defines a device for lysing comprising, in part, a lysing chamber and an ultrasonic transducer which is coupled to the wall of the lysing chamber. The claim does not specify a transmission media. The '174 patent discloses a similar lysing chamber in which is added deionized water as a transmission media (example #1).

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Accordingly, it would be obvious to one skilled in the art to include the transmission media disclosed in the US patent into the device claimed in the '541 patent especially in view of the fact that both devices are used for lysing.

11. Claims 83-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,431,476 B1 in view of USP 5,856,174 ('174). Claims 1-41 in the Taylor et al. patent defines a device for lysing comprising, in part, a lysing chamber and an piezoelectric ultrasonic transducer which is coupled to the wall of the lysing chamber. The claim does not specify a transmission media. The '174 patent discloses a similar lysing chamber in which is added deionized water as a transmission media (example #1). Accordingly, it would be obvious to one skilled in the art to include the transmission media disclosed in the US patent into the device claimed in the Taylor et al. patent especially in view of the fact that both devices are used for lysing.

12. Claims 83-85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/970,434 in view of USP 5,856,174 ('174) and USP 6,431,476 B1 (Taylor et al.). Claims 1-20 of the co-pending application 09/970,434 disclose a device for use with a transducer comprising a lysing chamber which includes a wall with an external surface for contacting the transducer. The claims do not specify a transmission media or piezoelectric transducer. The Taylor et al. patent claims a similar device which includes a piezoelectric transducer. The '174 patent discloses a similar device as claimed with the addition of adding a transmission media for lysing.

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Accordingly, it would have been obvious to one skilled in the art to provide the piezoelectric transducer disclosed in the Taylor et al. patent and the transmission media disclosed in example #1 of the '174 patent into the device of the 09/970,434 application in view of these elements known use for lysing.

This is a provisional obviousness-type double patenting rejection.

13. Claims 83-85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/006,904 in view of USP 5,856,174 ('174) and USP 6,431,476 B1 (Taylor et al.). Claims 1-4 of the co-pending application 10/006,904 disclose a device for use with a transducer comprising a lysing chamber which includes a wall with an external surface for contacting the transducer. The claims do not specify a transmission media or piezoelectric transducer. The Taylor et al. patent claims a similar device which includes a piezoelectric transducer. The '174 patent discloses a similar device as claimed with the addition of adding a transmission media for lysing. Accordingly, it would have been obvious to one skilled in the art to provide the piezoelectric transducer disclosed in the Taylor et al. patent and the transmission media disclosed in example #1 of the '174 patent into the device of the 10/006,904 application in view of these elements known use for lysing.

14. Claims 83-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-73 of U.S. Patent No. 6,440,725 B1 in view of USP 5,856,174 (Lipshutz et al.).

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Claims 1-73 in the '725 patent defines a device for lysing comprising, in part, a lysing chamber and a piezoelectric ultrasonic transducer which is coupled to the wall of the lysing chamber. The claim does not specify a transmission media. The '174 patent discloses a similar lysing chamber in which is added deionized water as a transmission media (example #1). Accordingly, it would be obvious to one skilled in the art to include the transmission media disclosed in the US patent into the device claimed in the '725 patent especially in view of the fact that both devices are used for lysing.

.15. Claims 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,168,948 B1 (Anderson et al.) in view of USP 5,856,174 ('174).

The Anderson et al. patent discloses an embodiment (figure 28) for controlling the degree of lyses. The device comprises an injected molded chamber 3006 (cavity) which is covered by a polymeric base 3004, which is considered to be equivalent to the claimed membrane. The base may be in the form of adhesive tape or thin film (col.42, line 28-30). The device further comprises a piezoelectric crystal 3002 coupled to a thinned wall 3020 of the base 3004 via a filled balloon. In use, the piezoelectric crystal 3002 generates acoustic energy that is directed into the chamber to cause cells within the chamber to lyse (col.42, lines 4-30). In example #1 of the Lipshutz et al. patent water is used as an ultrasonic transmission media for lysing cells in a similar device to that disclosed in the Anderson et al. patent. Accordingly, it would have been obvious to one skilled in the art to use the transmission media disclosed in the Lipshutz et al. patent in the device (figure 28) described in the Anderson et al. patent in view the disclosed use of both devices for cell lysis using ultrasonic energy.

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Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 703-308-3910. The examiner can normally be reached on M,T,Th,Fr, 7:30-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David A Redding
Primary Examiner
Art Unit 1744

D.A.R.
November 15, 2002



JACQUELINE M. STONE
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